

§ 890.5940

good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5975 Therapeutic vibrator.

(a) *Identification.* A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

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PART 892—RADIOLOGY DEVICES

Subpart A—General Provisions

Sec.

892.1 Scope.

892.3 Effective dates of requirement for pre-market approval.

892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

892.1000 Magnetic resonance diagnostic device.

892.1100 Scintillation (gamma) camera.

892.1110 Positron camera.

892.1130 Nuclear whole body counter.

892.1170 Bone densitometer.

892.1180 Bone sonometer.

892.1200 Emission computed tomography system.

892.1220 Fluorescent scanner.

892.1300 Nuclear rectilinear scanner.

892.1310 Nuclear tomography system.

892.1320 Nuclear uptake probe.

892.1330 Nuclear whole body scanner.

892.1350 Nuclear scanning bed.

892.1360 Radionuclide dose calibrator.

892.1370 Nuclear anthropomorphic phantom.

892.1380 Nuclear flood source phantom.

892.1390 Radionuclide rebreathing system.

892.1400 Nuclear sealed calibration source.

892.1410 Nuclear electrocardiograph synchronizer.

892.1420 Radionuclide test pattern phantom.

892.1540 Nonfetal ultrasonic monitor.

892.1550 Ultrasonic pulsed doppler imaging system.

892.1560 Ultrasonic pulsed echo imaging system.

892.1570 Diagnostic ultrasonic transducer.

892.1600 Angiographic x-ray system.

892.1610 Diagnostic x-ray beam-limiting device.

892.1620 Cine or spot fluorographic x-ray camera.

892.1630 Electrostatic x-ray imaging system.

892.1640 Radiographic film marking system.

892.1650 Image-intensified fluoroscopic x-ray system.

892.1660 Non-image-intensified fluoroscopic x-ray system.

892.1670 Spot-film device.

892.1680 Stationary x-ray system.

892.1700 Diagnostic x-ray high voltage generator.

892.1710 Mammographic x-ray system.

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892.1720 Mobile x-ray system.

892.1730 Photofluorographic x-ray system.

892.1740 Tomographic x-ray system.

892.1750 Computed tomography x-ray system.